

EFGCP-EUCROF Joint Workshop on
*Ethical Challenges in Clinical Research
at Both Ends of Life*

Common Lessons to be learnt from Paediatric & Geriatric Clinical Development

Crowne Plaza, Antwerp, Belgium

27 & 28 April 2010

organised by the



European Forum for Good Clinical Practice

&



European CRO Federation

www.efgcp.be – www.eucrof.eu

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Ethical Challenges in Clinical Research at both Ends of Life**
Crowne Plaza, Antwerp, Belgium, 27 & 28 April 2010
(Preliminary Programme, 22 March 2010 v5)

Workshop Rationale

Medical research and drug development are focused typically on an adult population of patients frequently excluding, at one end of the age spectrum, children and, at the other, the elderly and frail. Reasons for these exclusions are multiple and are not the same for both populations, but typical hurdles are shared as e.g. ethical concerns about informed consent, the need for specific formulations, specific adaptations of protocol procedures etc.

Therefore these vulnerable populations are today unrepresented in research and drug development. Once a drug is on the market and used, clinicians, patients and caregivers have to base their treatment decisions on empiric data and dose assumptions and not on scientific valid data.

This lack of data was already identified in the past, but specifically only for children. Thus drug development regulatory bodies, academia, researchers and patients' advocacy groups have recently agreed on improved and clear guidelines for research involving children. Much to be welcomed is the recently implemented, and in force in Europe since 2008, Paediatric Investigation Plan (PIP) for all new drugs in development.

At the other end of life, for the older and frail people, a lot of effort has still to be done as existing international recommendations and regulations are under review and the next steps to define what they will yield and how they will improve the situation are under discussion.

The European Forum for Good Clinical Practice (EFGCP) and The European CRO Federation (EUCROF) have thus brought together experts from both fields, experts in clinical research, ethics, social, patient organisations and pharmaceutical regulatory bodies to explore the shared ethical issues and to learn lessons from each other.

The objective of this workshop is to share concerns, to detect possible synergies and to learn from each other in order to improve and to facilitate and promulgate high quality ethical clinical research and drug development for these important populations across the whole of the European Union.

Programme Committee

Amparo Alemany Pozuelo	Paediatric Working Group, EUCROF & Trial Form Support Spain, Spain
Martine Dehlinger-Kremer	Paediatric Working Group, EUCROF & Omnicare Clinical Research, Germany
Piergiorgio Galletti	Paediatric Working Group, EUCROF & Hyperphar, Italy
Jean-Marc Husson	Geriatric Medicines Working Party, EFGCP & Eudipharm, France
Ingrid Klingmann	Chairman of the Board, EFGCP & Pharmaplex, Belgium
Klaus Rose	Children's Medicines Working Party, EFGCP & Granzer Regulatory Consulting & Services, Germany
Florian von Raison	Geriatric Medicines Working Party, EFGCP & Merck-Serono, Switzerland
Frank Wells	Ethics Working Party, EFGCP & Cambridgeshire 4 Research Ethics Committee, United Kingdom

Faculty

Amparo Alemany Pozuelo	Paediatric Working Group, EUCROF & Trial Form Support Spain, Spain
Jean-Pierre Baeyens	European Union Geriatric Medicine Society (EUGMS), Belgium
Michael Bone	Consultant Physician, EFGCP, United Kingdom

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Peter Crome	PREDICT Project, University of Keele, United Kingdom
Hugh Davies	National Research Ethics Service (NRES), United Kingdom
Martine Dehlinger-Kremer	Paediatric Working Group, EUCROF & Omnicare Clinical Research, Germany
François Hirsch	INSERM, France
Jean-Marc Husson	Geriatric Medicines Working Party, EFGCP & Eudipharma, France
Ingrid Klingmann	Chairman of the Board, EFGCP & Pharmaplex, Belgium
Anna Jurczynska	Paediatric Working Group, EUCROF & Quantum Experimental, Spain
Petra Knupfer	Baden-Württemberg Ethics Committee, Germany
Soeren Rasmussen	Pfizer, USA
Klaus Rose	Children's Medicines Working Party, EFGCP & Granzer Regulatory Consulting & Services, Germany
Helen Sammons	University of Nottingham, United Kingdom
Juergen Schaefer	Paediatric Working Group, EUCROF & Conreso, Germany
Nathalie Seigneuret	Human Medicines Special Areas, European Medicines Agency
Philippa Smit-Marshall	Paediatric Working Group, EUCROF & PharmaNet, The Netherlands
Florian von Raison	Geriatric Medicines Working Party, EFGCP & Merck-Serono, Switzerland
Frank Wells	Ethics Working Party, EFGCP & Cambridgeshire 4 Research Ethics Committee, United Kingdom

Workshop Language

The language of the Conference will be English.

Workshop Venue

Crowne Plaza Antwerp
G. Le Grellelaan 10
2020 Antwerp – Belgium
Tel: +32-3-259 75 00
Fax: + 32-3-216 02 96

Agenda

Tuesday, 27 April 2010

- 17:15 Registration
- 18:00 **Welcome and Introduction to the Workshop**
Ingrid Klingmann, Chairman of the Board, EFGCP & Pharmaplex, Belgium
Martine Dehlinger-Kremer, Paediatric Working Group, EUCROF & Omnicare Clinical Research, Germany
- 18:15 **Key Note Introductions**
- Unsolved Ethical Issues in Paediatric Clinical Research**
Helen Sammons, University of Nottingham, United Kingdom
- Unsolved Ethical Issues in Geriatric Clinical Research**
Jean-Pierre Baeyens, European Union Geriatric Medicine Society (EUGMS), Belgium
- 19:15 Dinner

Wednesday, 28 April 2010

- 8:00 Welcome Coffee

Plenary Session 1

Ethical Challenges in Paediatric Clinical Research

- Chairpersons:** *Klaus Rose, Children's Medicines Working Party, EFGCP & Granzer Regulatory Consulting & Services, Germany*
Amparo Alemany Pozuelo, Paediatric Working Group, EUCROF & Trial Form Support Spain, Spain
- 08:30 **Impact of the Paediatric Regulation on the Clinical Trial Environment**
Philippa Smit-Marshall, Paediatric Working Group, EUCROF & PharmaNet, The Netherlands
- 09:00 **Ethical Aspects of the Paediatric Investigation Plans (PIPs)**
Nathalie Seigneuret, Human Medicines Special Areas, European Medicines Agency
- 09:30 Discussion
- 10:00 Coffee Break

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Plenary Session 2

Ethical Challenges in Geriatric Clinical Research

- Chairpersons: *Florian von Raison*, Geriatric Medicines Working Party, EFGCP & Merck-Serono, Switzerland
Anna Jurczynska, Paediatric Working Group, EUCROF & Quantum Experimental, Spain
- 10:30 **Proposal for a Guideline on Performance of Clinical Trials in the Elderly Population**
François Hirsch, INSERM, France
- 11:00 **PREDICT: Increasing the PaRticipation of the ElDerly In Clinical Trials**
Peter Crome, PREDICT Project, University of Keele, United Kingdom
- 11:30 **Discussion**
- 12:00 **Discussion: Complex Considerations for Ethics Committees on a Trial in a Vulnerable Population**
Presenter of the "Difficult Case" and Facilitator: *Michael Bone*, Consultant Physician, EFGCP, United Kingdom
- 12:30 Lunch

Plenary Session 3

Lessons to be Learnt

- Chairpersons: *Soeren Rasmussen*, Pfizer, USA
Frank Wells, Ethics Working Party, EFGCP & Cambridgeshire 4 Research Ethics Committee, United Kingdom
- 13:30 **Similarities and Differences of the Informed Consent Process in Children and Old People**
Hugh Davies, National Research Ethics Service (NRES), United Kingdom
- 14:00 **How Can Ethics Committees Ensure Adequate Expertise for the Review of Paediatric and Geriatric Trials? – A Need for Training and Capacity Building**
Petra Knupfer, Baden-Württemberg Ethics Committee, Germany
- 14:30 **Discussion**
- 15:00 Coffee Break
- 15:20 **Open Forum Discussion: What Can Be Learned from the Regulatory Approach to Paediatric Drug Development for the Encouragement for Drug Development for the Elderly**
- Chairpersons: *Jean-Marc Husson*, Geriatric Medicines Working Party, EFGCP & Eudipharma, France
Juergen Schaefer, Paediatric Working Group, EUCROF & Conreso, Germany
- 16:15 **Closing Remarks**
Martine Dehlinger-Kremer, Paediatric Working Group, EUCROF & Omnicare Clinical Research, Germany
Ingrid Klingmann, Chairman of the Board, EFGCP & Pharmaplex, Belgium
- 16:20 **End of the Workshop**